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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,241

04/26/2006

Keiichi Fukuda

FUKUDA 15

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1444 7590 04/29/2008  
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

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1647

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,241	<b>Applicant(s)</b> FUKUDA ET AL.	
	<b>Examiner</b> ROBERT LANDSMAN	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7, 8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/26/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *1. Formal Matters*

- A. Applicant's election without traverse of Group I, claims 2-5 and 10, in the reply filed on 3/11/08 to the Restriction Requirement mailed 2/11/08 is acknowledged. Therefore, the Restriction is deemed proper and is made FINAL.
- B. Claims 2-5, 7, 8 and 10-12 are pending. Claims 7, 8, 11 and 12 are drawn to non-elected inventions. Therefore, claims 2-5 and 10 are the subject of this Office Action.

### *2. Specification*

- A. The title has been amended to "Methods of recruiting fibroblasts by administering G-CSF." If Applicants have any issue with this they are urged to submit a suggested title.
- B. The specification is objected to since the Brief Description of Figure 8 does not initially identify all the panels of that Figure (e.g. "Figures 8a - 8d show...")

### *3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claims 2-5 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using G-CSF to migrate fibroblasts into myocardial infarct lesions and alleviate cardiac remodeling in mice, does not reasonably provide enablement for a method of recruiting fibroblasts in general (claim 10), or to any wound site (claim 2) in any animal other than mice. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of

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experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive. Claim 10 simply recites “a method of recruiting fibroblasts...” Applicants have only provided guidance and working examples that administering G-CSF to mice can alleviate cardiac remodeling in mice. First, it is unclear as to whether or not the model used in the instant invention is an art-accepted model. Furthermore, claim 10 is drawn to a method of recruiting fibroblasts in any animal for any condition. Applicants have only demonstrated that recruitment occurs in myocardial infarct lesions and have not demonstrated that this recruitment occurs in other organs or tissue, or under any other conditions. Furthermore, in vitro recruitment has not been demonstrated. It is not known whether or not other factors (hormones, chemokines, etc.) found in vivo are required for this recruitment which would not be found in an in vitro setting.

#### ***4. Claim Rejections - 35 USC § 112, second paragraph***

A. Claims 2-5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim simply recites a method of recruiting fibroblasts by administering G-CSF. It is not clear how administering G-CSF to the skin, for example, would be able to recruit fibroblasts to the heart

#### ***5. Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 2-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Orlic et al. (PNAS 98(18):10344-10349, 2001). The instant claims recite a method of recruiting fibroblasts, including into

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wounded tissue, or the heart after the onset of heart disease, including MI, by administering G-CSF. Orlic teach the administration of G-CSF to mice after myocardial infarction. The recruitment of fibroblasts would have been an inherent property of G-CSF. Case law has established that a compound and all of its properties are inseparable, as are its processes and yields (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

B. Claims 2-5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta et al (US 7,220,407). The instant claims recite a method of recruiting fibroblasts, including into wounded tissue, or the heart after the onset of heart disease, including MI, by administering G-CSF. Mehta meet these limitations (Abstract). Myocardial infarction is considered by the Examiner as "wounded tissue" and is indicative of an onset of heart disease.

C. Claims 2-5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al (US 7,294,334). The instant claims recite a method of recruiting fibroblasts, including into wounded tissue, or the heart after the onset of heart disease, including MI, by administering G-CSF. Michal meet these limitations (Abstract and column 24, line 58 – column 25, line 21, especially line 14). Myocardial infarction is considered by the Examiner as "wounded tissue" and is indicative of an onset of heart disease.

## **6. Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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A. Claims 2-5 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 20060104942. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention are drawn to administering G-CSF to recruit fibroblasts to wounded tissue, including heart.

The '942 application is drawn to a method of treating ischemic disease by administering G-CSF and hepatocyte growth factor.

First, myocardial infarction, as recited in the instant claims, is an ischemic disease. Furthermore, the instant claims recite “comprising” which does not exclude the use of hepatocyte growth factor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

B. Claims 2-5 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 1 and 3 of copending Application No. 200400119184. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention are drawn to administering G-CSF to recruit fibroblasts to wounded tissue, including heart.

The '184 application is drawn to a method of treating ischemic disease by administering G-CSF and hepatocyte growth factor.

First, myocardial infarction, as recited in the instant claims, is an ischemic disease. Furthermore, the instant claims recite “comprising” which does not exclude the use of hepatocyte growth factor

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## **7. Conclusion**

A. No claim is allowable.

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***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/  
Primary Examiner, Art Unit 1647